UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/721,212	11/21/2000	William J. Boyle	A-451K	2270

21069 7590 03/22/2002

AMGEN INCORPORATED
MAIL STOP 27-4-A
ONE AMGEN CENTER DRIVE
THOUSAND OAKS, CA 91320-1799

EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	9

DATE MAILED: 03/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/721,212	Boyle
Examiner	**Art Unit**
Ron Schwadron	1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is **FINAL.** 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) X Claim(s) *1-42* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) X Claims *1-42* are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Interview Summary (PTO-413) Paper No. 5

18) Notice of Informal Patent Application (PTO-152)

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1,2,4-14 are drawn to nucleic acids, and host cells containing said nucleic acids, classified in Class 435, subclasses 320.1, 240.2 and 252.3, and Class 536, subclass 23.5.

II. Claim 15 is drawn to a process for producing a protein, classified in Class 435, subclass 69.1.

III. Claims 3,16-24,32,33,37,38 are drawn to a polypeptide and composition, classified in Class 530, subclass 350 and Class 514, subclass 2.

IV. Claims 25,26 are drawn to an antibody, classified in Class 530, subclass 387.1.

V. Claim 27 is drawn to a method of detection using an antibody, classified in Class 435, subclass 7.1.

VI. Claim 28-30 are drawn to a method of detection using an OPG binding protein, classified in Class 436, subclass 501.

VII. Claim 31 is drawn to a method of treatment using gene therapy, classified in Class 514, subclass 44.

VIII. Claims 34 and 35 are drawn to a method of treatment with soluble OPG binding protein, classified in Class 424, subclass 178.1

IX. Claims 34 and 36 are drawn to a method of treatment with an antibody, classified in Class 424, subclass 143.1.

X. Claims 39-41 are drawn to a method of preventing bone disease with soluble ODAR, classified in Class 514, subclass 8.

XI. Claim 42 is drawn to an in vitro assay using ODAR, classified in Class 435, subclass 7.2.

2. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein

3. Inventions I and VII are related as product and process of use. The inventions can be

shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in nucleic acid hybridization assays.

4. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used in nucleic acid hybridization assays.

5. Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used as an immunogen to produce antibodies which bind said molecule.

6. Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used as an immunogen to produce antibodies which bind said molecule.

7. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

specificity. In the instant case, the product as claimed can be used as to immunopurify OPG binding protein.

8. Inventions IV and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product as claimed can be used as to immunopurify OPG binding protein.

9. Inventions I,III,IV are different products. Proteins, antibodies and nucleic acids are distinct because they are structurally and functionally distinct and have different uses. The protein can be used in immunoassays to detect antibody, the antibody can be used in immunopurification methods, the nucleic acids can be used in nucleic acid hybridization assays. Therefore they are novel and unobvious in view of each other and are patentably distinct.

10. Inventions II,V-XI are different methods which use different ingredients to achieve different goals. Invention II is a method of producing a protein using recombinant DNA, while invention V is drawn to a method of detection using an antibody, while invention VI is drawn to a method of detection using an OPG binding protein, while invention VII is drawn to a method of treatment using gene therapy, while VIII is drawn to a method of treatment with soluble OPG binding protein, while invention IX is drawn to a method of treatment with an antibody. Inventions X is drawn to a method of preventing bone disease with soluble ODAR, while XI is drawn to an in vitro assay using ODAR, wherein said inventions use ODAR which is not used in the methods of inventions II, V-IX. Therefore they are novel and unobvious in view of each other and are patentably distinct.

11. Invention I is not used in the methods of inventions V/VI/IX-XI. Invention III is not used in the methods of inventions II/V/VII/IX/X. Invention IV is not used in the methods of inventions II/VI/VII/VIII//X/XI.

XI have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper. Therefore

they are novel and unobvious in view of each other and are patentably distinct.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00. The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644